



U.S. Food and Drug Administration  
Protecting and Promoting Public Health

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# Medical Device Use in the Home

## *The Users' Perspective*

*May 24, 2010*

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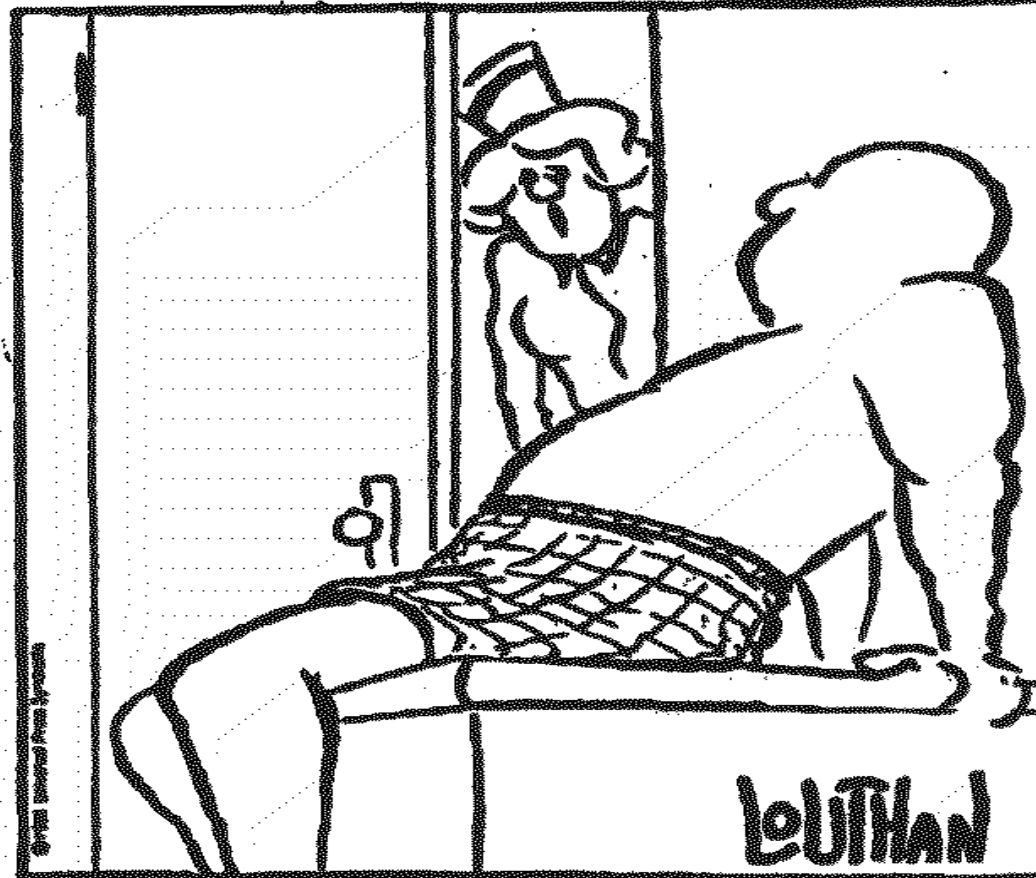
NATIONAL FAMILY CAREGIVERS ASSOCIATION

[www.thefamilycaregiver.org](http://www.thefamilycaregiver.org)



**BRIEFCASE**

**By John Louthan**



"You can get dressed now — the doctor  
saw you when you weren't looking."



# Equipment Can Give Life and Bring Quality to Life

- Christopher Reeve wouldn't have survived after his accident without the equipment that helped him breathe for eight years
- “I drive a Mercedes Dodge”



# What Characterizes Equipment

- Simple as a transfer belt
- Complex as a computer driven infusion pump or ventilator
- Manual, hydraulic, electric
- Multiple interconnected parts
- Maintenance free or requires regular maintenance



# It's About Communications

- Know your audience and target market
- Who is going to use and/or operate your products?
- What is their profile?
  - Physical
  - Emotional
  - Cognitive situation
  - Demographics
  - Their comfort with computers



# It's About Communications

- What kind of training will the user need?
- Who is going to provide it?
- How are you going to know they are using it correctly?
- How will you deal with consumer problems?



## Who Needs Equipment?

- There are 40 – 50 million Americans with disabilities
- Medicare's beneficiaries
  - 16% (7 million people) are under 65
  - 12% are over 85
- Boomers start turning 65 next year



## Who Cares for and Assists Persons with Chronic Conditions and Disabilities?

- Most people with chronic conditions or disabilities reside in the community
- Family caregivers provide 80% of all LTC services
- The use of paid help among family caregivers has declined in recent years.
  - From 41% - 35% between '04 and '09





# About Family Caregivers

- Multiple responsibilities and no time for themselves
- Majority are women – 60%
- Majority are working – 73% have been employed at some point while caregiving
- Extreme stress levels
- Health problems of their own, especially major depression
- Premature aging – as much as 10 years
- Reticent to ask for help
- **We are not trained**



# You Can't Make This Stuff Up

- Eve and the broken Hoyer lift
- Martha and the computer driven feeding tube



# Design with a *K/SS*

- Think i-phone and i-pad – intuitive, easy
- Think big buttons/easy to turn knobs, uncluttered face, etc.
- No small print please
- Build in a confidence-building feedback loop – signposts along the way for the user



# Recommendations for the FDA and Industry

- Nothing about me without me
  - Establish patient and family caregiver review panels
- Know your users
  - Age, physical situation, emotions, education
- *KISS*
- Instructions should be graphic as well as narrative with assurances along the way
- High quality customer service is critical



# A Caregiver's Poem

A wheelchair can be many things

It depends on your point of view



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# Thank You

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